

## REMARKS

### Claims Status

Claims 184-201 are pending and elected claims 184-186 are presented for examination.

### Rejection under 35 U.S.C. § 103

#### **A. Claims 184 and 185**

Claims 184 and 185 are rejected over Perkins *et al.* (USPN 3,861,400) in view of Newton Jr. *et al.* (USPN 3,957,060), Timko (WO/00/67558), Russell (Nicotine and Public Health, 2000), and Gibson (USPN 3,878,850). Office Action, pages 2-5.

Specifically, the PTO alleges “Perkins *et al.* disclose cigarettes with a tar to nicotine ratio between 3 and 8 (see Table I, examples 2, 4, and 6) and that the pH of the smoking material should be kept below approximately 6.5.” *Id.* at page 3. Yet, the PTO admits that “Perkins *et al.* do not disclose that the tar to nicotine ratio was measured by FTC or ISO methods, the use of transgenic *Nicotiana tabacum* to supply nicotine, or that the pH of the cigarette smoke produced has a pH of 6.5 or lower.” *Id.* To remedy these admitted deficiencies, the PTO relies on Timko, as “Timko *et al.* teach the engineering of *Nicotiana tabacum* to produce higher levels of nicotine using a heterologous coding sequence to boost levels of PMT which is an enzyme whose presence is a rate limiting step in supplying nicotine synthesis in tobacco.” *Id.* at page 4. The PTO cites Gibson for disclosing “a choky flavor is associated with an alkaline trend in pH of smoke” and Russell for disclosing specific tar to nicotine ratios. *Id.*

In so doing, the PTO alleges that it “would have been obvious to make the cigarette of Perkins *et al.* with the tobacco of Timko *et al.*, and adjust the pH to lower than 6.5 by the methods and materials of Gibson *et al.* if the pH of the smoke produced was alkaline in nature or produced “choky” flavor.” *Id.* at page 5. Applicants respectfully traverse the grounds for this rejection.

In order to validate a conclusion that a claim would have been obvious, the PTO must show that all recited elements of the claim were evidenced in the art. Further, the PTO must demonstrate that one of ordinary skill in the art could have combined the elements in the manner claimed, via known methodology, with no change in the respective function(s) of the elements and with the resultant combination yielding nothing more than predictable results. *KSR v. Teleflex*, 127 S. Ct. 1727, 1739 (2007).

If any of these requirements does not pertain, then the PTO is barred from concluding that the claim in question would have been obvious. Such is the case here because no reasonable combination of the references could have led the skilled artisan to a cigarette comprising a portion of an increased-nicotine transgenic *Nicotiana tabacum* plant, where the cigarette is characterized by (i) a tar-to-nicotine yield ratio of between about 3 and about 8, as measured by the FTC or ISO method, and (ii) cigarette smoke having a pH of about 6.5 or lower.

As background, applicants and PTO agree that primary reference, Perkins, discloses adding exogenous nicotine to increase the nicotine content of a smoking product. That is, Perkins teaches adding nicotine pectinate or nicotine alginate to reconstituted tobacco or a non-tobacco substitute material to increase the nicotine content of the resultant smoking product. In contrast, the instant tobacco itself has increased nicotine content without adding exogenous nicotine. Thus, through genetic engineering applicants remove the need for adding external nicotine sources to tobacco thereby facilitating cigarettes with increased nicotine and desirable tar-to-nicotine ratios.

The PTO is understood to take the position that it would have been obvious merely to “substitute” the tobacco product in Perkin’s cigarettes with the tobacco produced by Timko, because Timko allegedly produces increased nicotine tobacco by overexpressing PMT. Yet the PTO provides neither rationale nor motivation for such substitution. “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Because there is insufficient elaboration of any motivation or rationale for such substitution, the PTO improperly harnesses applicants' own specification to "reconstruct" applicants' own claimed cigarette. Such hindsight reconstruction can not be used for establishing obviousness, as the Federal Circuit has made clear that "Obviousness is determined as a matter of foresight, not hindsight." *KSR* at 421. Thus, for this reason alone, the rejection is improper and should be withdrawn.

In the absence of any evidence of record to the contrary, moreover, the PTO has not established that Perkin's tobacco product is essentially equivalent and thus amenable to substitution with Timko's tobacco. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicants' disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *See MPEP § 2144.06.* Here, the PTO provides neither evidence nor explanation for establishing any equivalency between Perkin's tobacco product and Timko's tobacco, let alone any reason for such substitution.

Even if the PTO had proffered rationale for equivalency between Perkin's tobacco product and Timko's tobacco, such rationale would surely fall short because Timko does not disclose tobacco plants overexpressing PMT with increased nicotine. That is, while Timko discloses PMT coding sequences, no where does Timko disclose overexpressing PMT to produce tobacco plants with increased nicotine levels. Thus, and contrary to the PTO's position, Timko does not disclose tobacco plants with increased nicotine.

Accordingly, no permutation of the cited art teaches or suggests genetically engineering tobacco to produce smoking articles having increased nicotine and decreased tar-to-nicotine ratio. Because the cited references therefore do not render the present claims obvious, the rejection should be withdrawn.

## **B. Claim 186**

Claim 186 is rejected over Perkins *et al.* (USPN 3,861,400), Newton Jr. *et al.* (USPN 3,957,060), Timko (WO/00/67558), Russell (Nicotine and Public Health, 2000), and Gibson

(USPN 3,878,850) as applied to claim 184 above, in further view of Conkling *et al.* (USPN 6,423,520). Office Action, pages 5 and 6.

Specifically, the PTO alleges “Timko *et al.* discloses uses genetic engineering to increase expression or production of PMT, but do not disclose up-regulating quinolate phosphoribosyl transferase (QPT or QPRTase).” *Id.* at page 5. The PTO relies on Conkling for “creating a transgenic *Nicotiana* having increased QPRT expression when compared to altering the expression of QPRTase by using complimentary nucleic acid sequences encoding a segment of QPRTase (abstract).” *Id.* In so doing, the PTO alleges “it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Timko *et al.* and Conkling *et al.* to increase production of the two different, known, rate limiting enzymes in the production of nicotine, and thus increasing nicotine production in transgenic plants that result from genetic manipulation.” *Id.* at page 5. Applicants respectfully traverse the grounds for this rejection.

As discussed above, no combination of the primary references teach or suggest genetically engineering tobacco to produce a cigarette with increased nicotine and a desirable tar-to-nicotine ratio. That is, because none of the cited references discloses increased nicotine plants, the primary references do not render the present claims obvious. Conkling does not remedy the admitted deficiencies of the primary references because Conkling likewise fails to suggest a cigarette made from genetically engineered tobacco with increased nicotine content.

Accordingly, no permutation of the cited references could render the present claims obvious, within the meaning of Section 103, and the rejection therefore should be withdrawn.

## CONCLUSION

Applicants submit that this application is in condition for allowance and they request an early indication to this effect. Examiner Felton is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.